



General

Guideline Title

Pegloticase for treating severe debilitating chronic tophaceous gout.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Pegloticase for treating severe debilitating chronic tophaceous gout. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 64 p. (Technology appraisal guidance; no. 291).

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Pegloticase is not recommended within its marketing authorisation, that is, for treating severe debilitating chronic tophaceous gout in adults who may also have erosive joint involvement and in whom xanthine oxidase inhibitors at the maximum medically appropriate dose have failed to normalise serum uric acid, or for whom these medicines are contraindicated.

People currently receiving pegloticase that is not recommended according to the above paragraph should be able to continue treatment until they and their clinician consider it appropriate to stop.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Severe chronic tophaceous gout

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Rheumatology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of pegloticase for treating severe debilitating chronic tophaceous gout

Target Population

Adult patients (aged ≥ 18 years) with severe refractory chronic gout who are symptomatic and have failed to normalise serum uric acid (SUA) with xanthine oxidase inhibitors (allopurinol and febuxostat) at the maximum medically appropriate dose, or for whom these medicines are contraindicated

Interventions and Practices Considered

Pegloticase (not recommended)

Major Outcomes Considered

- Clinical effectiveness
 - Serum and plasma urate levels
 - Gout flares
 - Tophus resolution
 - Pain
 - Tender and swollen joint count
 - Physical function
 - Adverse effects of treatment
 - Health-related quality of life (Health Assessment Questionnaire - Disability Index [HAQ-DI])
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The Evidence Review Group (ERG) report for this technology appraisal was prepared by School of Health Related Research (ScHARR) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Searches

Overall, the searches conducted for the sponsor submission appeared satisfactory. All strategies described in the methods were provided.

The search strategy for each database was provided. The reporting of the searches was confusing in places, making it difficult to replicate the searches. For the Medline and Cochrane Library search strategy, it was unclear whether subject headings or free-text terms were used for certain lines.

For the Medline Health Economic searches, the search strategy started at line #6 (confirmed by the manufacturer as an error). However, search line #11 combines search line #5 with terms for resource use, etc. It is therefore not possible to repeat line #11 of the Medline search and determine if the total number of hits reported is correct. For the Cochrane Library search re-running the search retrieved significantly more results than the 4 reported. However, if results from National Health Service Economic Evaluation Database (NHSEED) and Database of Abstracts of Reviews of Effectiveness (DARE) are included there are just 4 results. For the health economics search it would be appropriate to search just NHSEED and DARE and it might be that the reporting on the databases within the Cochrane Library was inaccurate for the health economics searches.

The number of database hits were provided for some but not all of the searches. For Embase, the number of records retrieved was provided for each line of the search strategy. For the clinical effectiveness searches database hits were not reported for databases other than Embase. This means that it is not possible to check if the number of hits from each database matches with the numbers given in the flow diagram.

For the Health Economic searches the number of database hits was reported for each line of the Embase search strategy. For the other database just the total number of hits was provided.

The search strategies appeared appropriate. The statement of the decision problem was illustrated using the PICO (population, intervention, comparison, and outcome) framework. PICO was applied correctly. The clinical effectiveness searches combined population, intervention and outcome terms. The inclusion of outcome terms helps to focus a search on relevant outcomes. However, terms related to outcomes might not be mentioned in the abstract meaning that the searches might not have retrieved all relevant references. The manufacturer confirmed that they considered it to be highly unlikely that a report of interest would not have included any of the outcomes of interest in the title or abstract. Combining the condition and intervention terms with a randomised controlled trial (RCT) filter would have been more appropriate to retrieve studies for clinical effectiveness. Additional searches could then be completed for references on quality of life, disability and pain. Alternatively, results for the intervention terms were small and would have produced a manageable number for sifting that would have ensured relevant references were not missed and also picked up the references around quality of life, disability and pain.

Subject headings were used on Embase appropriately. However, it was not clear if subject headings were used on Medline or the Cochrane Library. This made the replication of the searches difficult. Free-text terms were used in the searches. Attempts have been made to use synonyms for gout and pegloticase but they were not exhaustive or consistent. The brand name (KRYSTEXXA) was not included in the intervention term part of the clinical effectiveness and health economics searches. However, the manufacturer confirmed that papers which include the brand name would also include another relevant term already in the search strategy.

The described methods provide details of the sources searched. Date ranges of the databases would have been helpful for replication of the searches. For the Health Economics searches certain database should be searched as a minimum. The list includes EconLit which was not searched meaning that potentially relevant references might not have been retrieved. The manufacturer confirmed that they considered it highly unlikely that EconLit would yield additional studies of relevance for a UK decision context. Details of searches for conference proceedings and

company databases are provided. Hand searching is not reported.

An appropriate limit to humans was applied to the Embase and Medline search. The date range for the searches for conference proceedings was appropriately limited to 2005-2012.

Inclusion Criteria

The inclusion and exclusion criteria used in the selection of evidence for the systematic review of clinical effectiveness were presented in the manufacturer's submission (MS). The table in the MS was labelled as 'eligibility criteria used in search strategy' but was presented within the description of the study selection process. It was not clear from the MS how many reviewers were involved in the study selection process for the systematic review of clinical effectiveness. Best practice specifies that two reviewers be involved in the application of inclusion and exclusion criteria in order to limit bias in study selection. Details of the inclusion and exclusion criteria applied in the MS are presented in Table 2 of the ERG report (see the "Availability of Companion Documents" field).

See Sections 4.1.1 and 4.1.2 of the ERG report for additional information on clinical effectiveness search strategy (see the "Availability of Companion Documents" field).

Cost-Effectiveness

Objective and Search Strategy

A systematic search and review was conducted to address the following question: "What evidence exists for the cost-effectiveness of pegloticase for refractory chronic gout from a UK healthcare perspective?"

The manufacturer states that a comprehensive search was performed to identify the following three types of evidence for a refractory chronic gout patient population:

- UK economic evaluations for pegloticase
- The measurement and valuation of health (i.e., utility studies)
- UK resource utilisation studies (i.e., covering identification, measurement and valuation)

Overall, the searches conducted for the sponsor submission appear satisfactory. A detailed critique of this comprehensive search to identify economic evidence is described in Section 4.1.1. of the ERG report (see the "Availability of Companion Documents" field).

Inclusion/Exclusion Criteria

The key inclusion criteria for the search covered:

- Any full economic evaluation: cost-utility, cost-effectiveness, cost-benefit, cost-minimisation conducted in a UK specific setting.
- Comparators consisting of best supportive care or placebo
- Adult patients (aged ≥ 18 years) with severe refractory chronic gout who are symptomatic and have failed to normalise serum uric acid (SUA) with xanthine oxidase inhibitors (allopurinol and febuxostat) at the maximum medically appropriate dose, or for whom these medicines are contraindicated

The patient population specified were those expected to be covered by the pegloticase marketing authorisation at the time of the search. Whilst this differed slightly from the anticipated licensed indication at the time of submission, the ERG did not consider that this would result in any relevant information being excluded.

Number of Source Documents

Clinical Effectiveness

- Two phase III randomised controlled trials were included.
- One open-label extension study was also included.

Cost-Effectiveness

- No relevant economic evaluations were identified.
- The manufacturer presented an economic model.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The Evidence Review Group (ERG) report for this technology appraisal was prepared by School of Health Related Research (ScHARR) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Quality Assessment

See Table 3 of the ERG report for quality assessment results for C0405 and C0406 studies as presented in the manufacturer's submission (MS) (see the "Availability of Companion Documents" field).

Evidence Synthesis

Primary outcome data (proportion of plasma uric acid [UA] responders in each pegloticase treatment group versus in the placebo group, with a responder being defined as a patient with plasma UA less than 360 $\mu\text{mol/L}$ [6.0 mg/dL] for at least 80% of the time during months 3 and 6) were presented for each individual phase III trial and also as a simple pooled analysis (in which data were not meta-analysed but simply added together to yield a summary combined result). Data were also presented for secondary outcomes as simple pooled analyses only.

No meta-analyses of primary or secondary outcome data were included in the original MS, with the manufacturer describing meta-analyses as being "not-applicable." However, it has been argued that the simple pooling of data may yield counterintuitive or spurious results due to a phenomenon known as Simpson's paradox and that meta-analysis is a more valid approach to the quantitative combination of data.

The manufacturer provided primary efficacy outcome data for plasma uric acid (PUA) response for each phase III trial and also as a "combined" form. However, it was unclear from the clarification responses whether these "combined" data had been obtained by simple pooling or meta-analysis. The ERG subsequently undertook meta-analyses of data for PUA response and complete tophi resolution. Results are presented in Section 4.5 of the ERG report (see the "Availability of Companion Documents" field).

The manufacturer stated that subgroup analyses of the individual replicate phase III studies (C0405 and C0406) and of the pooled data for treatment responder and percent non-hyperuricaemic time were performed according to the following subgroups: gender, presence of tophi, body mass index (BMI) ($\leq 30 \text{ kg/m}^2$, $> 30 \text{ kg/m}^2$), age group (≤ 55 years, > 55 years), disease duration (< 5 years, ≥ 5 years), baseline Health Assessment Questionnaire - Disability Index (HAQ-DI) (≤ 1 , > 1), creatinine clearance ($< 50 \text{ mL/min}$, $\geq 50 \text{ mL/min}$) and antibody status. Although the ERG requested for results based on meta-analysed trial data from C0405 and C0406 to be provided, the manufacturer did not provide these on the basis that they considered that "pooling data of the two replicate trials is more appropriate than undertaking a meta-analysis with the same two studies." The ERG considers the use of meta-analysed data to be more robust than simple pooled data.

See Section 4 of the ERG report for more information on clinical effectiveness analysis (see the "Availability of Companion Documents" field).

Cost-Effectiveness

Model Structure

Health States

The model structure is described in the MS as being a decision tree coupled to a Markov model, although in practice the whole analysis is captured within the Markov framework without the need for a separate decision tree. Within the pegloticase arm, the first row of the Markov model is used to separate patients into the responder, non-responder and non-completer groups.

Serum uric acid (SUA) level is captured in the model using four health states: $<360 \mu\text{mol/L}$ (6.0 mg/dL); ≥ 360 - $<480 \mu\text{mol/L}$ (6.0-8.0 mg/dL); ≥ 480 - $<600 \mu\text{mol/L}$ (8.0-10.0 mg/dL); and $\geq 600 \mu\text{mol/L}$ (10.0 mg/dL). The MS states that health states based on SUA were selected as these were considered to correlate to disease severity, and expected impact on acute gout flares, potential for longer term development of tophi and patient quality of life. The ERG's clinical advisors were satisfied that long-term maintenance of SUA below $360 \mu\text{mol/L}$ (6.0 mg/dL) could be expected to result in clinically meaningful changes in patient related outcomes, although they noted that the British Society for Rheumatology (BSR) guideline recommends maintaining SUA levels below $300 \mu\text{mol/L}$. These health states defined by SUA were also the health states used in a cost-effectiveness analysis of febuxostat which formed part of Ipsen's submission to NICE for TA175.

There is also a death state allowing mortality to be captured within the model. In addition to capturing the distribution of patients across SUA levels, the model also tracks the frequency of flares and the proportion of patients with tophi resolution. The model uses a monthly cycle length for the duration of the 20 year time horizon and does not apply a half-cycle correction.

Transition Probabilities

The model estimates the distribution of patients across the four SUA levels by assuming a normal distribution around the mean SUA level for each group in the pegloticase arm (responders, non-responders, non-completers) and for the comparator arm population as a whole. This is done for each Markov cycle. So, whilst the model is described as being a Markov model and the structure shown in the MS has arrows showing transitions between the health states, no transition probabilities are used within the model to determine the distribution of patients between the health states defined by SUA level. Transitions to the death state are possible at any time and do not depend on the treatment being given or the patient's SUA level and are therefore the same across the whole population of the model. Transitions between different gout therapies are described in section 5.2.4.2 of the ERG report (see the "Availability of Companion Documents" field).

See Sections 5 and 6 of the ERG report for more information on economic analysis (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an "assessment report". Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from

nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the "appraisal consultation document" (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the "final appraisal determination" (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

The Committee considered the manufacturer's economic model, the assumptions on which the parameters in the model were based and the critique and exploratory analyses performed by the Evidence Review Group (ERG). It concluded that the structure of the manufacturer's model was acceptable but noted that there is uncertainty about the structural assumptions of the model. The Committee also took into account the manufacturer's revised model and additional evidence submitted during consultation and the ERG critique of these additional analyses.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee discussed that mortality derived from the general population may underestimate the mortality rate for patients with gout. The Committee concluded that although disease-specific values for mortality are desirable, in this instance the incremental cost-effectiveness ratios (ICERs) were not affected in a substantial way.

The Committee considered the modelling of the clinical-effectiveness data and noted the model assumes that all benefits gained in the first 6 months of pegloticase treatment would be sustained by maintenance treatment with allopurinol or febuxostat. The Committee discussed the study provided by the manufacturer in response to consultation to support the assumption that benefits of pegloticase therapy could be maintained by long-term treatment with allopurinol or febuxostat. The Committee concluded that there is substantial uncertainty about the long-term benefits of treatment assumed in the model.

The Committee noted that the utility values applied in the model were based on 3 outcomes: serum uric acid level, frequency of flares and tophi resolution. The Committee heard that frequency of flares was a function of serum uric acid level and that using both is 'double counting' the benefits of lowered serum uric acid level. The Committee heard that serum uric acid level is a biochemical marker and should not have been assumed to improve quality of life separately from the effect on flares and tophi. The Committee noted that there was no additional evidence to establish benefits from other symptoms and sequelae. It also learnt that in the trials, the term 'complete resolution' did not mean these patients would be free from all tophi although trial data for complete resolution were modelled as 'patients without tophi' and attributed higher utility gain than those with tophi, therefore perhaps overestimating the utility gain with tophi resolution.

Incorporation of Health-Related Quality-of-Life Benefits and Utility Values/Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The Committee was not presented with a case substantiated by data to show that pegloticase adds demonstrable and distinctive benefits of a substantial nature that have not already been adequately captured in the quality-adjusted life-year (QALY) measure presented in the economic model.

What Are the Key Drivers of Cost-Effectiveness?

The Committee concluded that duration of treatment in patients who have a response to pegloticase was a major driver of the ICER, which had been underestimated.

The Committee considered the effect of assuming no continued benefit after stopping pegloticase, that is, assuming that maintenance treatment with xanthine oxidase inhibitors does not maintain low serum uric acid levels. The Committee noted that this would decrease the incremental QALY gain and increase the incremental cost, so increasing the ICER. It concluded that the lack of long-term effectiveness data for allopurinol and febuxostat in patients who had been treated with pegloticase increased uncertainty in the estimation of the ICER.

The deterministic sensitivity analyses conducted by the manufacturer showed that the cost-effectiveness of pegloticase was particularly sensitive to changes in baseline levels of serum uric acid, the disutility associated with higher serum uric acid levels and patients' age. The sensitivity analyses also showed that the disutility associated with higher serum uric acid levels is a significant driver of cost-effectiveness. The cost-effectiveness results were also fairly sensitive to changes in the utility value for patients with serum uric acid levels under the target value and the baseline utility value. The cost-effectiveness results were also moderately sensitive to the parameter values for treatment efficacy and persistence with pegloticase treatment.

Most Likely Cost-Effectiveness Estimate (Given as an ICER)

The Committee concluded that the most plausible ICER would be in excess of £54,000 per QALY gained.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer of pegloticase and a review of this submission by the Evidence Review Group (ERG). For clinical effectiveness, three randomised controlled trials were the main source of evidence. For cost-effectiveness, the manufacturer's model and the additional economic analysis undertaken by the ERG were considered.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate recommendation regarding pegloticase for treating severe debilitating chronic tophaceous gout

Potential Harms

The most commonly occurring adverse reactions include: infusion-related reactions, gout flare, nausea, dermatitis, urticaria, pruritus, skin irritation, dry skin, anaphylaxis, influenza-like illness, joint swelling, vomiting and hyperglycaemia.

For full details of adverse reactions and contraindications, see the summary of product characteristics available at <http://emc.medicines.org.uk/>

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) has developed a costing statement explaining the resource impact of this guidance available on the NICE Web site (<http://guidance.nice.org.uk/TA291>).

Implementation Tools

Foreign Language Translations

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Pegloticase for treating severe debilitating chronic tophaceous gout. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 64 p. (Technology appraisal guidance; no. 291).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Jun

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Committee Members: Professor Andrew Stevens (*Chair*), Professor of Public Health, University of Birmingham; Professor Gary McVeigh (*Vice Chair*), Professor of Cardiovascular Medicine, Queens University Belfast and Consultant Physician, Belfast City Hospital; Dr David Black, Medical Director, NHS South Yorkshire and Bassetlaw; Dr Daniele Bryden, Consultant in Intensive Care Medicine and Anaesthesia, Sheffield Teaching Hospitals NHS Trust; Dr Andrew Burnett, Director for Health Improvement and Medical Director, NHS Barnet, London; David Chandler, Lay Member; Dr Mary Cooke, Lecturer, School of Nursing, Midwifery and Social Work, University of Manchester; Professor Peter Crome, Honorary Professor, Department of Primary Care and Population Health, University College London; Dr Maria Dyban, General Practitioner, Kings Road Surgery, Glasgow; Professor Rachel A Elliott, Lord Trent Professor of Medicines and Health, University of Nottingham; Dr Greg Fell, Consultant in Public Health, Bradford and Airedale Primary Care Trust; Dr Alan Haycox, Reader in Health Economics, University of Liverpool Management School; Professor Cathy Jackson, Professor of Primary Care Medicine, University of St Andrews; Dr Peter Jackson, Clinical Pharmacologist, University of Sheffield; Dr Janice Kohler, Senior Lecturer and Consultant in Paediatric Oncology, Southampton University Hospital Trust; Emily Lam, Lay Member; Dr Grant MacLaine, Director, Health Economics and Outcomes Research, BD, Oxford; Dr Andrea Manca, Health Economist and Senior Research Fellow, University of York; Henry Marsh, Consultant Neurosurgeon, St George's Hospital, London; Professor Eugene Milne, Deputy Regional Director of Public Health, North East Strategic Health Authority, Newcastle upon Tyne; Professor Stephen O'Brien, Professor of Haematology, Newcastle University; Dr Anna O'Neill, Deputy Head of Nursing & Healthcare School/Senior Clinical University Teacher, University of Glasgow; Professor Katherine Payne, Professor of Health Economics, University of Manchester; Dr Martin Price, Head of Outcomes Research, Janssen-Cilag, Buckinghamshire; Alan Rigby, Academic Reader, University of Hull; Dr Peter Selby, Consultant Physician, Central Manchester University Hospitals, NHS Foundation Trust; Dr Surinder Sethi, Consultant in Public

Health Medicine, North West Specialised Services Commissioning Team, Warrington; Dr John Stevens, Lecturer in Bayesian Statistics in Health Economics, School of Health and Related Research, Sheffield; Prof Matt Stevenson, Technical Director, School of Health and Related Research, University of Sheffield; Dr Judith Wardle, Lay Member

Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) .

Availability of Companion Documents

The following are available:

- Archer, R., Davis, S., Uttley, L., and Cantrell, A. Pegloticase for the treatment of hyperuricaemia in people with symptomatic gout whose disease is refractory to conventional urate-lowering therapy, or in whom conventional urate-lowering therapy is contraindicated or not tolerated. Technology Assessment Report. Sheffield (UK): School of Health and Related Research (SchARR), The University of Sheffield. 2012 Oct 16. 154 p. Electronic copies: Available in Portable Document Format (PDF) from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) .
- Pegloticase for treating severe debilitating chronic tophaceous gout. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 4 p. (Technology appraisal 291). Electronic copies: Available in PDF from the [NICE Web site](#) .

Patient Resources

The following is available:

- Pegloticase for severe, chronic gout with tophi. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 6 p. (Technology appraisal 291). Electronic copies: Available in Portable Document Format (PDF) from the [National Institute for Health and Care Excellence \(NICE\) Web site](#). Also available in Welsh from the [NICE Web site](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on September 23, 2013.

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